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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
STOKLOSA, JOSEPH A	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,177	STICKNEY ET AL.	
	Examiner	Art Unit	
	JOSEPH STOKLOSA	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/28/2008 has been entered.

Claim Rejections - 35 USC § 102/103

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-3, 7-8, 15-19, 21, 24, 27-31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kramer (US 5,405,362).

6. Kramer et al. disclose an interactive defibrillation and drug injection system that obtains and analyzes physical parameters such as an ECG signal or blood pressure (Col. 11, line 5-8), automatically determining the magnitude of which to apply a pacing stimuli, based at least in part of the physical parameters, such as the a p-wave, QRS complex, R-wave that was measured (Col. 14, line 13-23; Fig. 18F, 840), and supplying the pacing stimuli at a the determined magnitude and at a pacing rate (Col. 14, line 13-23).

7. It is noted that the limitation "automatically determining a magnitude," is satisfied by Kramer et al. in that Kramer et al. states "selectable quantities... directions from the CPU" as set forth in Col. 14, line 13-23.

8. Examiner considers the device to perform the step of analyzing, creating therapy parameters such as the stimulus magnitude, and delivery in that although Kramer discloses the system to be interactive, Kramer further discloses that these functions are

performed by the "expert system" in through the use of therapy and diagnostic algorithms (e.g. Col. 11, line 35-48).

9. In the alternative it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Kramer with eliminating system dependency on user input, in other words making the system automatic, since such a modification would provide the predictable results of providing quicker therapy by eliminating an intermediate step and providing greater patient safety by removing human error. Further it has been held that broadly providing an automatic means to replace manual activity which has accomplished the same results involves only routine skill in the art. *In re Venner,* 120 USPQ 192.

10. With regard to claim 2, Kramer et al. disclose comparing physical parameters to predetermined parameters (800) indicative of severe bradycardia (Fig. 18F).

11. With regard to claim 3, Kramer et al. disclose comparing measured parameters to predetermined parameters indicating ventricular standstill (Col. 11, 24-34).

12. With regard to claim 7 and 8, Kramer et al. disclose determining if a shock has been delivered within a predetermined period of time (Fig. 18B, 420) as well as obtaining and analyzing updated parameters (Fig. 18B, 430).

13. With regard to claims 15-19, 21, Kramer et al. disclose delivering various non-electrotherapeutic treatments (18A, 18C). It is noted that CPR includes oxygen therapy and therefore the claim limitation of 19 is satisfied. In the alternative, it would have been obvious to one having ordinary skill in the art to modify the method taught by Kramer et

al. with providing oxygen therapy, since such a modification would provide the patient with oxygen in the presence of a cardiac condition that is limiting oxygen circulation throughout the body.

14. With regards to claims 27-29, Kramer et al. disclose a controller that indicates whether further treatment is needed and determine a physical status (18A). Kramer et al. also disclose a user interface such as a keyboard or in the alternative yes or no buttons (Col. 13, lines 13-20).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer et al. in view of Kroll et al. (US 6,167,306).

17. Kramer et al. disclose the claimed invention except for detecting low cardiac output. Kroll et al. teach that it is known to detect the presence of low cardiac output (claim 39). Low cardiac output could be indicative of a block in the heart and would indicate that the patient needs stimulation in order to allow the heart to beat at a normal pace. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Kramer et al., with

detecting low cardiac output as taught by Kroll et al., since such a modification would provide the system with a method of determining if stimulation therapy is needed.

18. Claims 4-5, 8-17, 20, 23, 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer et al. in view of Snyder et al. (US 6,356,785).

19. With regard to claims 4 and 5, Kramer et al. disclose the claimed invention except for comparing the physical parameters to predetermined parameters indicating a 2nd or 3rd degree atrioventricular block. Snyder teaches comparing parameters to determine the presence of a 2nd or 3rd degree block as set forth in Col. 18, line 41-44 to provide proper treatment such as transcutaneous pacing. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Kramer et al. with comparing the physical parameters to predetermined parameters indicating a 2nd or 3rd degree atrioventricular block as taught by Snyder et al. since such a modification would provide for data to base proper treatment such as transcutaneous pacing.

20. With regard to claims 8-9 and 20, 25, Kramer et al. disclose the claimed invention except for automatically adjusting the pacing stimulus based on the updated parameters. Snyder et al. teach adjusting the pacing stimulus based on the updated parameters, including blood oxygen levels, as set forth in figures 15, 16B, and 17B to provide proper therapy for the current state of the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the

system as taught by Kramer et al. with adjusting the pacing stimulus based on the updated parameters as taught by Snyder et al. since such a modification would provide the system with adjusting the pacing stimulus based on the updated parameters for providing proper therapy for the current state of the patient.

21. With regard to claims 10 and 26, Kramer et al. disclose the claimed except terminating therapy based upon the updated physical parameters. Snyder et al. do teach terminating therapy based upon the updated physical parameters if the parameters indicate normal cardiac rhythm (see column 21, lines 36-39 and column 17, lines 10-18). Terminating the therapy once normal cardiac rhythm has been determined would be beneficial to the patient in order to prevent inducing an arrhythmia. Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the defibrillating and pacing taught by Kramer et al. with the early termination of therapy once normal cardiac rhythm has been detected in order to prevent inducing an arrhythmia.

22. With reference to claims 15 and 17, Kramer et al. teaches the defibrillating and pacing as described above, but does not teach determining if the heart condition would be appropriately treated with non-electrotherapeutic treatment. Snyder et al. teaches determining if the heart condition would be appropriately treated with non-electrotherapeutic treatment (see figure 4 and column 9, lines 63-67 and column 10, lines 1-6). Not all abnormal heart rhythms can be best treated by defibrillation, and therefore, attempting to treat them with defibrillation can cause damage to the heart. Therefore, it would have been obvious to one skilled in the art at the time the invention

was disclosed to combine the defibrillating and pacing taught by Kramer et al. with the non-electrotherapeutic treatment in order to prevent causing damage to the heart.

23. With regards to claims 16 and 23, Kramer et al. teaches the defibrillating and pacing as described above, but does not teach indicating the physical status of the patient to the user. Snyder et al. do teach indicating the physical status of the patient to the user (see column 10, lines 3-6 and column 6, lines 42-51). Alerting the user to the physical status of the user allows the user to deliver the proper therapy to the patient. Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the defibrillating and pacing taught by Kramer et al. with the indicating the physical status of the patient to the user so that the user can deliver the proper therapy to the patient.

24. With regards to claims 11-14, Kramer et al. in view of Snyder teach that it is known to identify and determine if pacing should be ceased based on updated parameters; however fail to teach the specific parameters including no electrical capture, no mechanical capture, failure of improvement in cardiac output, and adequate circulation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Kramer et al. in view of Snyder et al. with the specific parameters including no electrical capture, no mechanical capture, failure of improvement in cardiac output, and adequate circulation since it was known in the art that the specific parameters including no electrical capture, no mechanical capture, failure of improvement in cardiac output, and adequate circulation

is used to provide indication whether a pacing pulse would be beneficial or detrimental to the patient.

25. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer et al. in view of Snyder et al. as applied above and further in view of Sherman et al. (US 2001/0018562).

26. Kramer et al. in view of Snyder et al. teach the claimed invention except for monitoring the patient end tidal CO_2 level. Sherman et al teach monitoring the patient's end tidal CO_2 level as set forth in page 4, paragraph 27 to provide indication of how well the heart is circulating blood. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Kramer et al. in view of Snyder et al. with monitoring the patient's end tidal CO_2 level as taught by Sherman et al., since such a modification would provide the method with an indication of how well the heart is circulating blood.

Response to Arguments

27. Applicant's arguments with respect to claims 1-31 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH STOKLOSA whose telephone number is (571)272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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7/3/2008